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| EXAMINER | |
|---|---|
| SHAY, DAVID M | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/751,472 | MODY ET AL. | |
| | Examiner | Art Unit | |
| | david shay | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *October 25, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,5-22,25-33,40-54,58-91,97,100-107,225,229-255,282 and 284-301* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-22,25-33,40-54,58-91,97,100-107,225,229-255,282 and 284-301* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In response to the objection to the drawings, applicant notes that 37 CFR 1.81(a) states, in part that applicant "is required to furnish a drawing of his or her invention where necessary for the understanding of the subject matter sought to be patented" and goes on to deride the examiner for simultaneously taking official notice of various notorious expedients in the art, stating the it is "difficult to logically square" the taking of official notice with the requirement to provide an illustration of the elements which are the subject of the drawing objection. The examiner respectfully notes, however, that a careful reading of the previous office action will reveal that the drawing objection therein is based on 37 CFR 1.83(a) rather than 1.81(a). And as explicitly stated in the first sentence of 37 CFR 1.83(a) "The drawing in a nonprovisional application must show every feature of the invention specified in the claims", the examiner has been able to find no waiver of this requirement for notorious expedients, and respectfully requests applicant to indicate the specific portion of the rule where any such waiver may be found.

Applicants assert that the final office action of July 25, 2007 was improperly made final and admonishes the examiner for failing to respond to the substance of the arguments presented with regard to the new matter objection. The examiner apologizes for the oversight with led to the repetition of an objection which was no longer appropriate, and by way of response to the remarks and amendments, notes that, while the cancellation of the language makes the objection moot, the examiner notes that the objection was justified in that the language of the phrase included the positioning the delivery portion in positions which would locate it within the materials making up the interior walls of the distal end, which positions would still be "within the distal end portion, but which positions are clearly not enabled or contemplated by the

originally filed disclosure. The foregoing similarly applies to the rejection of claim 107 under 35 U.S.C. 112, first paragraph.

Next applicants note that as the examiner has not identified the patent number of the Roth et al reference with specificity, and that the reference to Roth et al is presumed to refer to U. S. Patent No. 5,207,672. The examiner notes that this is correct, the reference to Roth et al, was indeed intended to refer to the only reference of record to a first named author of Roth but including additional authors, and which was coincidentally noted on the 892 (Notice of References Cited) which accompanied the office action first containing a rejection based on Roth et al.

Then applicants take issue with the examiner's removal of the rejection of claim 106 under 35 U.S.C. 102(b) as clearly anticipated by Roth and subsequently reiterating the rejection after further amendments to the claim, all of which were further limiting. The examiner must respectfully note that while it is incumbent upon the examiner to apply art to claims which are not patentable, to the best of the examiner's knowledge, there is no requirement that the examiner apply every possible art rejection that can possibly be made to the claims, the examiner must chose between the rejections and present those which are best. As an example, in the examiner's view, the Sinofsky reference is the best rejection for the claims in terms of teachings (the examiner acknowledges that applicants differ with him on this point, but none the less this is the examiner's position), however, as the Sinofsky reference is only applicable under 35 U.S.C. 102(e), this may not be the best reference in terms of filing date. Thus references such as Bednarek et al (U. S. Patent No. 5,785,706) were subsequently applied, which not only read on the claims, but were, in the examiner's view more closely related to the preferred embodiment of

the invention as disclosed. Thus, contrary to applicants' assertion, the examiner had not "decided that Roth et al was overcome by a broader version of claim 106", only that Bednarek et al was a superior reference, which could properly be applied due to applicants' amendments. Once applicants responded by amending around the Bednarek et al reference, by requiring that the end portion be devoid of openings, the Roth et al reference became, once again, the best reference in terms of art that was applicable under 35 U.S.C. 102(b).

Turning now, to applicants' arguments with regards to the substance of the Roth et al reference, applicants argued that the object of Roth et al "is to damage tissue by coagulation necrosis, so that the tissue dies and is sloughed off during urination" and goes on to state that "[A]ablation according to the present invention causes a lesion of scar tissue which is not sloughed off, but remains to function as an electrical conduction block". While applicants' position is noted, the examiner must respectfully point out that the claims must be given their broadest reasonable interpretation in view of the specification. The specification, while mentioning terms with the root "ablate" many times, gives little indication of what this process id to be considered to be restricted to for the purposes of the disclosure of the invention. From paragraphs [0022], [005], and [0056], among others it seems the energy must be "strong enough" to perform ablation. Similarly, from at least paragraph [0098], it appears that the mechanism of ablation, at least as it relates to microwave application, is that the tissue is heated. The the originally filed disclosure, with relation to the use of lasers, states, at [0127]: "In accordance with another aspect of the present invention, the ablative energy may be in the form of laser energy sufficient to ablate tissue. Example of such laser components include CO.sub.2 or Nd:YAG lasers." Finally, the originally filed disclosure states, at [0146] "A closed ablation path may also

utilized to ablate around an aneurysm, such as a cardiac aneurysm or tumor, or any kink of tumor. In other example, the ablation sheath can be inserted in an organ in order to ablate a deep tumor or to perform any surgical treatment where a tissue ablation is required." Thus the examiner was unable to find anything substantially restricting the allowable broadest reasonable interpretation of the term "ablate" and its roots in the context of the instant claims. The term "ablate" is defined as "to remove or destroy the function of." (Stedman's Medical Dictionary, 26th Edition). Clearly the method disclosed by Roth et al produces this effect as well. Further the examiner notes that the laser described by Roth et al is an Nd:YAG (see column 12, lines 21-40), the same laser which the originally filed disclosure specifically states produces ablation energy. Similarly, the term "transmural", while appearing throughout the specification is not clearly defined therein. A reasonable interpretation of the term "transmural" is "Through any wall, as of the body or of a cyst or any hollow organ" (Stedman's Medical Dictionary, 26th Edition). The term "wall" is similarly not defined in the originally filed disclosure. A reasonable interpretation of the term "wall" is "An investing part enclosing a cavity, such as the chest or abdomen, or covering a cell or any anatomical unit. A wall as of the chest, abdomen or any hollow organ." (Stedman's Medical Dictionary, 26th Edition). Clearly from the foregoing, the term "transmurally" cannot be confined to cutting through the entirety of the prostate, as applicants appear to suggest in the remarks. It is clear that the term "transmurally" could equally properly be applied to the epithelial lining if the urethra, or any subset of the various cell layers making up the urethra itself, especially where it is covered by the prostate. Clearly, the distal end of the Roth et al device is devoid of holes (see Figure 6 thereof) and the energy delivery portion is slidably positioned within the distal end to emit ablative (Nd:YAG laser) energy

radially through a contact surface of the distal end. And also clearly, sufficient energy is delivered to ablate tissue (within the broadest reasonable interpretation of this term) wherein a lesion formed by the ablation forms a conduction block through the entire wall thickness (see Figures 9, 10, and 11A-C, and column 13, line 60 to column 17, line 15). Clearly at least the vaporized portion of the urethral wall will from a conduction block, in actuality, the conduction block will extend to the level wherein the tissue is necrotized and beyond to the point where the tissue is affected similarly to the cardiac ablation method of applicants. Thus claim 106 is clearly anticipated by the disclosure of Roth et al.

Turning now to applicants' remarks concerning the Sinofsky et al, the examiner had attempted to address applicants' arguments concerning the applicability of the Sinofsky et al reference to the claims. Specifically at pages 3-5 of the office action mailed July 25, 2007 the examiner. By way of further explanation, it is clear, that as the optical fiber moves, the diffusing element must also move (e.g. by compression thereof), the diffusing element is also part of the "energy delivery portion" and clearly emits light radially.

With regard to the application of Sinofsky et al to claim 107, applicants traverse the examiners determination that the device of Sinofsky et al can be said to fulfill the limitation that the device be slidably position the delivery portion "while preventing rotation of said energy delivery portion relative to said guide catheter". Applicants argue that there is no motivation to prevent rotation of the emitter, since the same pattern of light would be produced, regardless of the relative rotational position of the fiber and the ablation element. Further applicants argue that the examiner's conclusion that the fiber would not rotate in the passage is erroneous purportedly because "[T]the maximum outside diameter of the fiber 18 shown at the distal end of the device

is in Fig. 2 [of Sinofsky et al] is about 7.5 mm" and also because the "minimum inside diameter of the passage formed by element 12 is about 9 mm" thus leading applicants to the conclusion that rotation of the fiber in such a device would not be prevented. The examiner is curious to know from whence applicants have determined the sizes of the fiber and the passage, since Sinofsky et al make mention of no absolute or relative sizes of the elements whatsoever and given that it is "well-known that drawings are not considered to be drawn to scale" (see the instant response at page 30, last sentence of the second paragraph). Similarly, given the lack of scale in the drawings, it is unclear from whence applicants derive their conclusion that "there is clearly a large tolerance shown between the two elements in Fig. 2", especially in view of showing in Fig. 2 of Sinofsky et al that the terminus of the fiber, which appears just to the left of the line delineating the centerline of the vertical portion of the handle at the bottom of Fig. 2, being circumferentially coextensive with the circumference of the diffuser 32 of the ablation element 12. This aside, however, even assuming *arguendo*, that a "substantial gap" could be inferred from the drawings, one of ordinary skill in the art would immediately realize that this was simply an exaggerated showing of the feature, since in any actual device, any substantial gap would enable the end of the fiber to become somewhat misaligned, either axially, rotationally, or both, with the curving passage, which would cause binding of the fiber in the passage as the sheer face of the fiber met the passage wall at an angle, thereby presenting the abrupt corner formed by the interface of the flat face and the oval side portion to the passage wall. This would ultimately result in one of the fiber's being irreversibly wedged in the passage, which would cause the light from the fiber to be principally directed to and out of the passage wall, rather than to the scattering element; the passage to be perforated by the fiber as it is forced forward which

would cause all the light to be directed out of the passage and away from the scattering element; or breakage of the fiber, which would cause a substantial portion of the light to be reflected back to the fiber input from each crack or fracture induced in the fiber. However to the extent that any gap per se can be inferred from the illustrations of Sinofsky et al, the examiner must note that one of ordinary skill in the art would readily perceive that any gap between the fiber exterior and the interior passage wall would simply be the minimal gap provided to allow the fiber to slide without binding against the passage wall. As such, this would constitute a structure which would serve the function of "preventing rotation of said energy delivery portion relative to said guide catheter" as currently claimed. With regard applicants' comment that the examiner regarded applicants arguments wherein element 12 was referred to as the ablation device by itself, the examiner notes that at no time was this statement made by the examiner. The examiner simply stated that it appeared that applicants argued that the housing was the ablation device itself, not "by itself".

With regard to applicants' assertion that the oval cross sectioned fiber of Sinofsky et al does not have a "radially asymmetric geometry", the examiner must respectfully disagree. Firstly, the examiner must point out that, regardless of whether or not applicants' interpretation of the term "radially asymmetric" is correct (and the examiner emphatically maintains that it is not) the device still reads on the claim language of both claims 107 (for the reasons enumerated above) and 225 (which recites a "lumen having a radially asymmetric geometry" – applicants have argued the fiber configuration). That said, the examiner must submit that applicants' definition of "radially asymmetric" as not only requiring that a cross section be radially asymmetric, but that the cross section also lacks line symmetry with respect to axes

perpendicular to the axis by which radial asymmetry is determined, is strained. By the definition applicants are putting forth in the paragraph bridging pages 30 and 31 of the instant response, a square cross section would be considered radially symmetric (i.e. not radially asymmetric), since situating the square along two perpendicular axes which pass through the corners of the square would show that the square is linearly symmetrical about these two axes. The interpretation of the term "radially asymmetric" as used in the claims must correspond to the broadest reasonable interpretation, as this term lacks positive antecedent basis in the specification as originally filed. Further, as the mechanical keys, which are defined in the originally filed disclosure as the structure which "continuously aligns a window portion 58 of the energy delivery portion" (see the originally filed disclosure page 21, lines 7-27) include oval configurations (see original Figure 20A and the originally filed disclosure page 45, lines 16-21) applicants' attempt to assert that the claim language should be read to exclude the oval configuration of Sinofsky et al must fail. The foregoing is equally applicable to the arguments regarding this claimed feature with respect to claims 225, 293, 297 and any other claims which contain this feature. The examiner would also respectfully point out that while applicants note that any gap "would clearly allow at least partial rotation of element 18 relative to element 12" (see the instant response, page 31, third full paragraph, emphasis added), the instant claims cannot be interpreted to require that no rotation occur between the sheath and the ablative device, since the originally filed disclosure only supports rotation of the ablation element (see the originally filed disclosure, page 50, first paragraph) or a configuration wherein the sheath and the ablative element are configured such that "dimensional tolerances therebetween should be sufficiently large to enable smooth relative advancement…" (originally filed disclosure, the paragraph spanning pages 22 and 23), which

configuration would "allow at least partial rotation of" the ablation element and the ablation sheath. The examiner has been unable to locate any disclosure in the originally filed disclosure which allows no rotation whatsoever. Given this, the Sinofsky et al reference as described above reads on any reasonable interpretation of the current claims in light of the specification as originally filed.

With respect to the creation of overlapping lesions, Sinofsky et al clearly teaches this e.g. at column 4, lines 24-25. Thus applicants' arguments of this feature being lacking in Sinofsky et al must fail with respect to claims 246, 248, 249, and any other claim purporting to contain this feature. Thus it is the examiner's view that the anticipation rejection based on Sinofsky et al is proper, as set forth above.

With respect to the rejection under 35 U.S.C. 103 over Bednarek et al in combination with Sinofsky et al, applicants note that contrary to the examiner's description of the references the claims involved that none of the claims recite "a rotationally asymmetric cross-section". However, while this phrase may be absent from the claims, the structures described by this term still fulfill the recitation of "maintaining rotational alignment" which is contained in the claims to which the combination is applied. Continuing, applicants argue that neither reference teaches such maintaining and that Sinofsky et al teach against it, however, this assertion is erroneous, as already set forth above, in view of the teachings fairly found within the four corners of the reference, and the definitions which must be ascribed to the claim terms in view of the interpretation thereof in light of the originally filed disclosure.

With reference to the particular claims argued by applicant, the key assembly of claims 51, 54, 59 and 64 is not taught, this is clearly erroneous in view of the oval configuration of

Sinofsky et al, which is specifically designated as a key assembly configuration in Fig. 20A of the originally filed disclosure, as set forth above. With respect to claims 52 and 53, the examiner notes that Sinofsky et al clearly teach the desirability of providing directionalized, substantially radial energy application (see e.g. Fig. 4), which ensures the creation of a uniform lesion, and as one of ordinary skill in the art would immediately perceive, would also require a less powerful source of ablative energy, since energy that would otherwise be lost to surrounding tissue is now directed towards performing the surgery. The examiner also notes that Bednarek teach the use of microwaves as an equivalent to laser energy for the formation of lesions such as those produced by the device and method of Sinofsky et al. Thus, the use of directionalized microwave emitters being known in the art (see e.g. U. S. Patent No. 5,314,466, cited at page 4 of the originally filed disclosure), would be employed by one of ordinary skill in the art for the same reasons as the unidirectional laser emitter would be used. Further with regard to claim 64, Bednarek et al also teach the equivalence of ultrasound as an equivalent to laser energy etc. for creating lesions. Thus this claim reads on the applied combination. With regard to claim 100, Bednarek discloses that the electrodes need not contact the tissue (see column 8, lines 44-52), thus clearly the intervening material, which is considered part of the window, is conductive, else the RF energy would not reach the tissue to be ablated. With regard to claim 101, the examiner notes firstly, that one of ordinary skill in the art would desire to allow the maximum energy transfer between the device and the tissue, this by itself would impel one of ordinary skill in the art to employ a material with the coefficient claimed, but Sinofsky et al also teach that TEFLON® is desirable to use as the contact element, since it prevents tissue adhesion, it is noted that TEFLON® is also disclosed as one of applicants' preferred materials for transmitting microwaves. Thus the

rejection of claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71, 72, 86, 87, 89-91, 97, 100-103, 296, 298, and 299 is proper.

Applicants emphasize the difference between taking official notice that key assemblies are known, and the assertion that it would have been obvious to apply key assemblies in the prior art references, asserting that the surgeon need only look at the orientation of the device in his hand. Ignoring for the moment that firstly, the key assembly of Sinofsky et al is exactly that shown in Figure 20A of the originally filed disclosure and secondly that the examiner merely took official notice that the use of key assemblies were known for alignment purposes; the orientation of devices which are used endocardially cannot be determined by "simply looking" as applicant asserts. If this were so, applicants' provision of the rotational alignment features would be superfluous. With regard to the various elements of the procedure that the examiner has taken official notice of, applicants request for the provision of a reference or affidavit, which appears throughout the arguments, is noted, but is not seasonable. The officially noticed facts set forth in the office action of June 7, 2005. These officially noticed facts were not challenged in the immediately succeeding response of December 14, 2005, instead applicant merely argued the patentability of the claims as based on the patentability of claim 1, which rejection at that time did (and even currently, claim 1 does) not involve the features of which official notice was taken. Therefore, while applicants request now for affidavit or other evidentiary showings on the part of the examiner regarding these officially noticed facts of the office action of June 7, 2005 are noted, they are not seasonable.

With regard to applicant's assertion that "Sinofsky et al appears to provide no teachings to procedures" and that Bednarek et al and Cox et al teach only endocardial procedures,

applicants' attention is respectfully invited to the paragraph bridging pages 11 and 12 of Cox et al and Sinofsky et al specifically discuss both endocardial and epicardial application in e.g. claims 31 and 32 thereof. Thus applicants' allegations with respect to claim 282 are not convincing. Further, the remainder of applicants' arguments, drawn to the patentability of various claims based on the patentability of claim 1, are similarly not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed October 25, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "wherein said at least one lumen is offset from a central longitudinal axis of said sheath".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim 301 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on "wherein said at least one lumen is offset from a central longitudinal axis of said sheath" and the originally filed drawing Figures 7 and 8 clearly show the lumen encompassing the longitudinal axis of the sheath.

Claim 106 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roth et al.

Claim 106, 107, 225, 240, 243, 246, 248, 249, 253, 293-295, and 297 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sinofsky et al.

See Figures 1-7 and column 1, line 34 to column 4, line 25, the non-circular cross section being illustrated in Figure 2, the insertion of the optical fiber occurring e.g. during the manufacture of the device.

Claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71, 72, 86, 87, 89-91, 97, 100-103, 296, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al. Bednarek et al teach a method such as claimed (see Figures 1-8 and column 12, lines 15-29) except the maintaining of rotational alignment. Sinofsky et al teach a cardiac ablation device employing a slidably positionable ablation element with a rotationally asymmetric cross section positioned in sheath in a lumen with a complimentary shape wherein the energy can be directionalized. It would have been obvious to the artisan of ordinary skill to employ the rotationally asymmetric cross section lumen and ablative element of Sinofsky et al in the method of Bednarik et al, since this would enable less energy to be used in the procedure, since more of it would be directed towards the tissue while assuring that the operative direction could be reliably pointed towards the tissue of interest, or to include the various types of ablation energy and the various procedural steps of Bednarik et al in the method of Sinofsky et al, since the various energies are equivalents, as taught by Bednarik et al and Sinofsky et al do not elucidate the procedural steps required to approach the heart intravenously, to employ the jugular vein, since this is a large vessel in the neck, and to configure the ablative element to directionalize the energy or employ an cryosurgical element, since this does not manipulatively affect the method, thus producing a method such as claimed.

Claims 6-8, 12, 13, 17-22, 40-42, 70, 78, 79, 104, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71, 72, 86, 87, 89-91, 97, 100-105, 296, 298, and 299 above, and further in combination with Cox et al (WO '187) and the admitted prior art of simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures. Cox et al (WO '187) teach the equivalence of laser, ultrasound, microwave, and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped; use of a sheath with a cut out window; and various manipulations of the device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. It would have been obvious to the artisan of ordinary skill to employ the maze procedure and ablation means of Cox et al (WO '187) in the combined method of Bednarek et al in combination with Sinofsky et al, or to employ the particular ablation steps of the combined teachings of Bednarek et al in combination with Sinofsky et al in the method of Cox et al (WO '187) since Cox et al (WO '187) teach no particular form for the non-cryogenic ablation elements; to employ the various non cryogenic directional ablation element features

claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al (WO '187), such as directionality with these equivalent forms of ablation energy discussed by Cox et al (WO '187); to include a cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable, official notice of which is hereby taken; as well as to position the device adjacent to or in contact with the oblique or transverse sinuses as these are both structures associated with pulmonary veins and would be contacted in conjunction with the procedure shown in figure 21 of Cox et al (WO '187); to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art; official notice of all of these having already been taken and to perform a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures official notice of which is hereby taken thus producing a method such as claimed.

Claims 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 5-8, 12, 13, 17-22, 25-33, 40-42, 46-54, 58-72, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 above, and further in combination with Swanson et al. Swanson et al teach using temperatures sensors to control ablation and electrodes to pace, map, etc. the heart in

a maze procedure wherein the pulmonary vein is encircled. It would have been obvious to the artisan of ordinary skill to employ the sensors and the pulmonary vein encircling device in the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187), since this would enable the performance of beneficial cardiac procedures such as maze or to employ the longitudinally translatable ablation element of the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) in the method of Swanson et al, since this can create longer lesions with a single ablation element, this producing a method such as claimed.

Claims 80-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 5-8, 12, 13, 17-22, 25-33, 40-42, 46-54, 58-72, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 above, and further in view of Kesten et al. Kesten et al teach delivering ablation devices with a pre-shaped sleeve to reach the ventricles via peripheral veins. It would have been obvious to the artisan of ordinary skills to employ the sheath, delivering route, and treatment region of Kesten et al in the combined method Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) or to employ the directional slidable probe in a sheath of the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) in the method of Kesten et al, since this would allow the treatment of an elongated area without repositioning the device and in either case to treat one of the atria or ventricles since these chambers are the site of beneficial treatments, official notice of which has already been taken and to employ an alternate access route such as the jugular or subclavian vein, since these

are recognized catheter insertion routes in the art, official notice of which has already been taken, thus producing a method such as claimed.

Applicant's arguments filed October 25, 2007 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/david shay/

Primary Examiner, Art Unit 3735